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U J ZUVI PATENT NON-FINAL

PATENT APPLN. NO. 10/521,439 RESPONSE UNDER 37 C.F.R. \$1.111

REMARKS

Prior to discussing the present action, applicants would like to thank Examiner Christopher Koharski for the courteous and helpful telephone interview extended to applicants' undersigned representative on July 31, 2007. The content of the interview is discussed hereinbelow.

Claims 1-22 [sic, claims 1 to 11?] are rejected in the Action under 35 U.S.C. 102(b) as being anticipated by Gauthier et al. (U.S. Patent No. 4,976,683) (hereinafter: "Gauthier"). The Office states in the rejection that Gauthier discloses a peritoneal dialyzer that includes each of the elements recited in claim 1 and a pump; and discloses albumin as the osmotic agent. The Office also alleges that Gauthier discloses a method including each of the claimed steps.

Gauthier discloses a continuous ambulatory peritoneal dialysis (CAPD) method and does not explicitly disclose a peritoneal dialyzer. Therefore, the Examiner's interpretation of the claims of the present application and interpretation of Gauthier in the statement of rejection do not appear to be correct and are unclear to applicants. For example, it is unclear whether the Office is interpreting the term "dialyzer" as including the peritoneal cavity; interpreting the mechanism for dehydrating the peritoneal

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dialysate as being the removal of the dialysate from the peritoneal cavity; and/or taking the position that a means of measuring an osmotic agent concentration in the peritoneal dialysate and provided in the peritoneal circuit on the side of the end at which the catheter is connected with respect to the dialyzer would be inherent in the method of Gauthier.

In view of applicants' lack of understanding of the position of the Examiner in the rejection, applicants' undersigned representative attempted to contact the Examiner that issued the Action, Examiner Melissa A. McCorkle, to request an interview to clarify the Office's interpretation of the claims and of the Gauthier reference. The undersigned representative was advised that Examiner McCorkle was no longer with the Office and that examination of the application had been assigned to Examiner Koharski. The undersigned contacted Examiner Koharski and Examiner Koharski agreed to the telephone interview on July 31, 2007.

During the interview on July 31, 2007, Examiner Koharski explained that he had reviewed the Gauthier reference prior to the interview, but only for the elements following the "characterized in that" clause in claim 1. The undersigned understood that Examiner Koharski's reasons for limiting his consideration of the reference are, first, that the use of the "characterized in that"

language suggests to him that the novel aspects of the dialyzer are the elements recited after "characterized in that" and, second, that he had only limited time to review the Gauthier reference. Mr. Koharski explained that, based on his review, the means capable of measuring an osmotic agent concentration in the peritoneal dialysate recited in claim 1 of the present application appears to be inherent in the method of Gauthier and that the limitations in claims 1 and 7 regarding dehydrating the peritoneal dialysate could read on the addition of osmotic agent to the dialysate of Gauthier.

Applicants do not agree that the limitation in the claims of the present application regarding dehydrating the peritoneal dialysate can be reasonably interpreted as reading on an addition of osmotic agent to a dialysate. The dictionary meaning of "dehydrate" is "to remove water or moisture from" (Merriam Webster's Unabridged Dictionary", Copyright 2003, Version 3). See also "The American Heritage Dictionary", Third Edition, Version 3.6a, 1994. Adding osmotic agent to the dialysis composition in Gauthier does not remove water from the dialysis composition. Moreover, although not discussed during the interview, and regardless of other possible differences between the peritoneal dialyzer and method of peritoneal dialysis of the present invention and the "apparatus" and method disclosed in Gauthier, applicants do

not believe that Gauthier can be interpreted as including a dialyzer comprising a hemodialysate circuit and a hollow fiber membrane.

Notwithstanding that applicants do not believe that the disclosure of Gauthier can be interpreted as meeting each of the limitations of the original claims of the present application (including those recited prior to the "characterized in that" phrase, claims 1 and 7 of the application have been amended to precisely recite the dialyzer and method of dialysis of the present invention. The claims as amended remove possible interpretations of the peritoneal dialyzer and method of peritoneal dialysis of the present invention as reading on the disclosure of Gauthier.

More particularly, claim 1 has been amended to recite that the peritoneal dialysate circuit (and, thus, also the dialyzer provided in the peritoneal dialysate circuit) is external of the patient and to recite that "the peritoneal dialysate in the peritoneal dialysate circuit contacts the hemodialysate in the hemodialysate circuit via the membrane of said dialyzer and water in the peritoneal dialysate is removed to the hemodialysate via said dialyzer by said dehydrating mechanism". Claim 7 has been amended to recite that in the peritoneal dialyzer used in the method of the invention the peritoneal dialysate circuit is external of the

patient and to recite, in step (c), water is removed "by a dehydrating mechanism in which the peritoneal dialysate in the peritoneal dialysate circuit contacts the hemodialysate in the hemodialysate circuit via the membrane of said dialyzer and water in the peritoneal dialysate is removed to the hemodialysate via said dialyzer".

These amendments are believed to clearly distinguish the present application over Gauthier. The dehydrating of peritoneal dialysate as recited in the amended claims cannot be properly interpreted as reading on the addition of osmotic agent to the dialysate as in Gauthier.

For the above reasons, removal of the 35 U.S.C. 102(b) rejection of the claims is believed to be in order and is respectfully requested.

Request for Interview Prior to Next Action

The undersigned respectfully requests that in the event the claims of the present application as amended are not found to be allowable, the Examiner contact the undersigned vis telephone prior to taking further action in the present application to discuss the foregoing amendments and arguments. During the interview on July 31, 2007, Mr. Koharski kindly agreed to grant such interview.

The foregoing is believed to be a complete and proper response to the Office Action dated April 11, 2007, and is believed to provide a proper summary of the telephone interview on July 31, 2007. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted, KUBOVCIK & KUBOVCIK

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